

### **REMARKS**

Applicants acknowledge receipt of an Office Action dated June 25, 2007. Applicants acknowledge the finality of the Restriction Requirement, and the withdrawal of rejections previously made in the September 8, 2006, Office Action. Claims 58-64 remain rejected. Reconsideration of the present application is respectfully requested in view of the foregoing amendments and the remarks which follow.

#### **I. Status of the Claims**

Claims 58-62 and 64 are pending, with claim 58 being the sole independent claim. Claim 58 is amended to better define Applicants' invention. Claim 63 is canceled solely to advance prosecution and not in acquiescence to the PTO's rejection. Accordingly, the foregoing amendments to the claims do not introduce new matter. Their consideration and entry are respectfully requested.

#### **II. Rejections Under 35 U.S.C. § 101**

On page 2 of the Office Action, the PTO rejected claim 58 under 35 U.S.C. § 101 because the claimed invention allegedly encompasses non-statutory subject matter. The PTO's rejection is overcome in view of the amendment to claim 58, following the suggestion of the Examiner. Applicants respectfully request that the PTO withdraw the rejection.

#### **III. Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement**

In the Office Action at pages 7-12, and 13-16, the PTO reasserted the prior rejection of claim 63 as allegedly failing to comply with the enablement requirement under 35 U.S.C. § 112, first paragraph. Applicants traverse. However, solely to advance prosecution, and not in acquiescence to the rejection, claim 63 is canceled. The cancellation of claim 63 renders moot the rejection.

#### **IV. Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description**

On pages 3-7, the PTO newly rejected claims 58-64 as failing to comply with the written description requirement under 35 U.S.C. § 112, first paragraph. The rejection is based

on the assertion that Applicants' description of a single species, SEQ ID NO:127, provides insufficient representative species for a claim to the genus of amino acids that are 90% identical to SEQ ID NO:127 and which possess the function of binding to livin- $\beta$ . Applicants respectfully traverse the rejection.

A single embodiment can be more than sufficient for written description of a genus. *See, e.g. Capon v Eshhar*, 418 F.3d 1349 (Fed. Cir. 2006); *Invitrogen Corp. v Clontech Labs, Inc.*, (429 F3d 1052 (Fed Cir 2005)). In the present case, those of ordinary skill can readily identify every single structural variant within the claimed genus by the disclosure of the common structure, SEQ ID NO:127. The remaining functional element, binding to livin- $\beta$ , can be determined by no more than routine experimentation, following the examples and protocols provided by the specification. As MPEP § 2163 states:

Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

Because the determination of the functional element is routine and does not require undue experimentation, the amount of structural information that needs to be provided is correspondingly reduced.

In making the rejection, the PTO cites to *Regents of the University of California v Eli Lilly and Co.* 119 F.3d 1559 (Fed. Cir. 1997), and *Enzo Biochem, Inc. v. Gen-Probe Inc.* 296 F.3d 1316 (Fed. Cir. 2002) in support of the proposition that Applicants must provide further written description support for the claimed functional element. In *Eli Lilly*, the underlying patent disclosed the sequence of rat insulin and sought to claim human insulin. Providing the *structure* of rat insulin was insufficient to cover all proteins of the same *function*, regardless of the structure. The failure to define and claim a common *structure* in *Eli Lilly* is therefore *unlike* the present case, in which Applicants seek to claim a genus with a shared structure, that is then *further limited* by a functional element.

In *Enzo*, the court examined the sufficiency of written description in the absence of a complete written structure, but where a functional definition was provided, *i.e.* hybridization

to a probe that was deposited at ATCC. The Federal Circuit found that this combination of partial structure and a functional definition sufficed for written description. Applicants situation is stronger than *Enzo*, because a genus of complete structures are provided first, and are then further limited by a functional limitation.

To summarize, Applicants have provided a working example of SEQ ID NO:127, with a known and defined sequence and a corresponding function. Applicants are not seeking to claim other peptides which share only the same function, as with *Eli Lilly*. Rather, Applicants seek to claim a limited genus that is defined according to a shared *structure*, and then *further limit* that genus by a functional limitation.

For at least these reasons, the written description rejections are overcome, and reconsideration and withdrawal of the rejection is respectfully requested.


### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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